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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#12
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In re application of

Docket No: Q63988

Izumu SAITO, et al.

Appln. No.: 09/807,223

Group Art Unit: 1642

Confirmation No.: 5950

Examiner: Unknown

Filed: April 11, 2001

For: RECOMBINASE-EXPRESSING CELLS

STATEMENT UNDER 37 C.F.R. § 1.97(e)

Commissioner for Patents
Washington, D.C. 20231

Sir:

The undersigned hereby states, upon information and belief:

That References 7, 8, 9, and 11 cited in the Information Disclosure Statement filed concurrently herewith were first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement. The remaining references were previously cited and submitted to the U.S. Patent and Trademark Office.

Respectfully submitted,

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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

1. WO 92/15694 issued September 17, 1992. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated August 9, 2002.)
2. SAUER et al., Site-Specific DNA Recombination in mammalian Cells by the CRE Recombinase of Bacteriophage P1", *Proceedings of the National Academy of Sciences of USA*, Vol. 85, No. 14, July 1, 1988, pages 5166-5170. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated August 9, 2002.)
3. WO 97/32481 issued September 12, 1997. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated August 9, 2002.)
4. PARKS et al., "A helper-dependent adenovirus vector system: Removal of helper virus by Cre-mediated excision of the viral packaging signal", *Proceedings of the*

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National Academy of Sciences of the United States, Vol. 93, No. 24, 1996, pages 13565-13570. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated June 13, 2001.)

5. LIEBER et al., "Recombinant adenoviruses with large deletions generated by Cre-mediated excision exhibit different biological properties compared with first-generation vectors in vitro and in vivo", *Journal of Virology*, Vol. 70, No. 12, 1996, pp. 8944-8960. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated June 13, 2001.)
6. KANEGAE et al., "Efficient gene activation system on mammalian cell chromosomes using recombinant adenovirus producing Cre recombinase", *Gene* (Amsterdam), Vol. 181, No. 1-2, 1996, pp. 207-212. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated August 9, 2002.)
7. O'GORMAN et al., "Recombinase-Mediated Gene Activation and Site-Specific Integration in Mammalian Cells", *Science*, Vol. 241, March 15, 1991, pp. 1351-1355.
8. ZOLOTUKHIN et al., "A Humanized Green Fluorescent Protein CDNA Adapted for High-Level Expression in Mammalian Cells", *Journal of Virology*, Vol. 70, No. 7, July 1, 1996, pp. 4646-4654.
9. BUCHHOLZ et al., "Improved properties of FLP recombinase evolved by cycling mutagenesis", *Nature Biotechnology*, Vol. 16, No. 7, July 1998, pp. 657-662.
10. KILBY et al., "Site-specific recombinases: tools for genome engineering", *Trends in Genetics*, Elsevier Science Publishers, Vol. 9, No. 12, December 1, 1993, pp. 413-421. (This reference was previously submitted to the U.S. PTO with an Information Disclosure Statement dated August 9, 2002.)
11. WO 99/25841 published May 27, 1999.

One copy of References 7, 8, 9, and 11 above is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date for an application other than a continued prosecution application (CPA) under §1.53(d); (2) Before the mailing date of the first Office Action on the

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merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



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Date: November 26, 2002